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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,170	12/22/2003	Anke Esperester	1/1445US	7746

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,170	ESPERESTER ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/4/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-30* is/are pending in the application.

4a) Of the above claim(s) *17-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-16,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-30 are pending in the application, claims 29-30 being newly added in the amendment submitted on 8/4/06.

Claims 17-28 remain withdrawn, being directed toward a non-elected invention, elected without traverse in the response filed 9/21/05.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

The previous rejection made under 35 USC 112 First paragraph has been removed due to Applicant's amendments to the claims.

The previous rejection made under 35 USC 102(e) has been removed due to Applicant's statement that the previous patent and this application, at the time the invention was made (filed) was currently owned by the same assignee as that of Esperester et al. (US 6,485,727 B1).

The previous rejection made under 35 USC 102(b) has been removed due to Applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

Claims 1, 4, 6-16 and 29-30 are rejected under 35 U.S.C. 103(a) as being obvious over Ables, E (3,136,693) in view of Struengmann (US 6,284,269).

The teachings of Ables, E (3,136,693) were discussed *supra*. Ables did not specifically teach wherein the tablet contained a disintegrant such as colloidal, anhydrous silica, a binder such as microcrystalline cellulose, a filler such as hydrogen phosphate or magnesium stearate, a plasticizer, a colorant or the particular amounts of each constituent in the tablet.

The teachings of Struengmann (US 6,284,269) were discussed *supra*. To reiterate, Struengmann (US 6,284,269) disclosed conventional tablet additives such as hydrogen phosphate, colloidal anhydrous silica, sodium starch, magnesium stearate, microcrystalline cellulose (see example V/7, col's 10-11) as well as plasticizers such as polyethylene glycol (see claim 10). Thus, it was known that all of the tablet ingredients as Instantly claimed were conventional tablet ingredients, known at the time the invention was made.

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of

components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. Although the prior art do not teach the particular combination of carriers which are added to the red vine extract or all the various permutations of concentration ranges as claimed, it would be conventional and within the skill of the art to identify the optional concentrations of a given excipient because (1) the selection of appropriate concentration of excipients to stabilize red vine extract for the intended purpose of preventing its denaturation and decomposition during storage are conventional and within the skill in the art, and (2) hydrogen phosphate, colloidal anhydrous silica, sodium starch, magnesium stearate, microcrystalline cellulose and polyethylene glycol are well known in the art as excipients to used for tableting active ingredients.

Applicant's arguments were fully considered, but not found persuasive.

Appilcant initially argues that the references " do not disclose or even suggest a tablet having enhanced stability wherein the tablet shoes an enhanced stability." (pp. 13-14, Remarks". In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,

208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This rejection was based upon the combination of the references. It is deemed that the prior art clearly suggested the claimed combination of elements in that Ables teaches water and hydroalcoholic (water/alcohol) extracts of red vine leaves for medicinal use (see columns 2-30). It remains deemed that the types/amounts of excipients as Instantly claimed would have been obvious to one of ordinary skill in the art at the time the invention was made in view of Struengmann who taught that silica was a conventional additive to tablet formulations. Although neither reference specifically taught a tablet having 'enhanced stability', this statement does not hold much patentable weight in that the term is very broad. It is deemed that a tablet comprising any excipient would have 'enhanced stability' over a tablet which did not have an excipient. The amounts as found in claims 29 and 30 are deemed obvious for the same reasoning as set forth in the previous Office action and above.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

December 21, 2006